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510(K) SUMMARY

Submitted by:

Jennifer M. Paine
Associate II, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Name/Classification of Device

Infusion Pump/ Class II, 80FRN – 21 CFR 880.5725

Trade Names:

Colleague® Volumetric Infusion Pump
Colleague® CX Volumetric Infusion Pump

Predicate Device:

Colleague® Volumetric Infusion Pump, #K953098 cleared on 12/22/95

Statement of Intended Use:

Colleague® Volumetric Infusion Pumps are electronic infusion pumps indicated for continuous or intermittent delivery of solutions through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural or irrigation of fluid spaces.

Device Description:

Colleague® pumps use a shuttle and valve control system mechanism to provide accurate, continuous infusions. The pumps operate on 90 - 260 VAC, 50/60 Hz or on an optional 12 VDC power jack for an external power source. Alternatively, power may be supplied from rechargeable batteries integral to the device. Colleague provides continuous infusion and combined modes of operation. The pumps have configurable input parameters, which allow institutions to pre-select which modes of operation will be available to users and which units of measure will be used for data entry.

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Baxter Healthcare proposes to modify the predicate device to upgrade the currently marketed device and to add a line-extension to be called the Colleague® CX pump. The principal modifications described in this submission are: (1) addition of a new product code with a color display and an additional software feature (Colleague® CX pump, 2M8161); (2) enhancement and addition of software features.

Summary of Technological Characteristics of New Device to Predicate Devices

The technological features of the modified Colleague® Volumetric Infusion Pumps do not differ significantly from the currently marketed Colleague® Volumetric Infusion Pump. The subject and predicate devices are similar in design, material composition, components, labeling, and manufacturing processes. The subject and predicate devices are identical in intended use. There are technological differences between the subject and predicate devices, but these differences do not raise new issues of safety and effectiveness.

Discussion of Non Clinical Tests; Conclusions Drawn from Nonclinical Tests

The results of testing conducted to verify the design modifications demonstrate acceptable performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2000

Ms. Jennifer M. Paine
Associate II, Regulatory Affairs
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K002211
Trade Name: Colleague CX Volumetric Infusion Pump 2M8161 and Volumeter
Regulatory Class: II
Product Code: FRN
Dated: July 20, 2000
Received: July 21, 2000

Dear Ms. Paine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Colleague® and Colleague ® CX Volumetric Infusion Pumps

Indications For Use:

The Baxter Colleague® Volumetric Infusion Pump and Colleague® CX Volumetric Infusion Pump are designed to meet the fluid delivery needs of today's evolving health care environment. These pumps can be utilized for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous (IV), intra-arterial (IA), subcutaneous, epidural or irrigation of fluid spaces applications.

Fluid delivery applications include:

* parenteral fluids, drugs and electrolytes (e.g. cardiovascular drugs, antibiotics, anesthetics, analgesics, chemotherapy agents, total parenteral nutrition products, lipids, solutions for irrigation procedures, etc.); and
* whole blood and blood products.

The Colleague® Volumetric Infusion Pump and Colleague® CX Volumetric Infusion Pump are designed to travel the continuum of care, following the patient into a variety of care areas, including, but not limited to:

- Hospital:
  - General Floor
  - Medical/Surgical
  - Critical/Intensive Care Areas
  - Pediatrics/Neonatal
  - Labor/Delivery/Post Partum
  - OR/Anesthesia
  - Post Anesthesia/Recovery
  - Cardiac Catheter Lab
  - Emergency Room
  - Burn/Trauma Units
  - Oncology
- Mobile Intensive Care
- Homecare
- Blood Centers
- Nuclear Medicine
- Hospice
- Subacute Facilities
- Outpatient/Surgical Centers
- Long Term Care
- Nursing Homes

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division **Sign-Off**)
Division **of Dental, Infection** Control,
and **General Hospital Devic**es
510(k) **Number** K002211

JUL. 20 2000*